REMARKS

Claims 1-4, 6 and 13-16 are canceled herein, without prejudice.

Claim 10 is amended herein. Support for the amendment is found, for example, in the paragraph bridging pages 29-30 of the specification. No new matter is presented.

I. Response to Claim Rejection - 35 U.S.C. §101

Claim 1, 3, 13-16 are rejected under 35 U.S.C. §101 allegedly because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101.

Without conceding the merits of the rejection, claims 1, 3 and 13-16 are canceled herein thereby rendering the rejection moot as to these claims.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 101.

II. Response to Claim Rejections - 35 U.S.C. § 112

Claims 1-2, 4, 6 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Without conceding the merits of the rejection, claims 1-2, 4 and 6 are cancelled herein, thereby obviating the rejection. Accordingly, Applicants respectfully request withdrawal of the rejections.

III. Response to Obviousness-Type Double Patenting Rejection

Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-13 of Umejima et al., US 2008/0103171.

Without conceding the merits of the rejection, Applicants respectfully defer responding to the rejection and request that the rejection be held in abeyance.

IV. Respnose to Prior Art Rejections

Claims 10, 12 and 17 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Slatter et al., US 2004/0138253.

Claims 10, 12 and 17 are rejected under 35 U.S.C.§ 102(e) as allegedly being anticipated by Fraser et al., US 2004/0198822.

Claims 10, 12 and 17 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Saito et al., US 2005/0181031.

Claims 10, 12 and 17 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Fraser et al., US 2005/0239890.

Applicants respectfully traverse.

Slatter et al

As previously noted, Slatter et al does not disclose, teach or suggest the existence of amorphous solifenacin or a composition of solifenacin or a salt thereof for use in a solid formulation. Thus, for at least this reason, Slatter et al does not anticipate the present invention.

Further, although Slatter et al describes various compounds as anti-muscarinic agents, Slatter et al does not disclose, teach or suggest a specific embodiment of a pharmaceutical composition of solifenacin and a salt thereof containing crystalline and amorphous solifenacin or a crystalline and amorphous salt thereof, together with an inhibitor of an amorphous preparation which is a substance having an ethylene oxide side chain as required in claim 10. For this additional reason, the present invention is not anticipated by Slatter et al.

Moreover, Slatter et al does not disclose, teach or suggest a substance having an ethylene oxide chain, as an inhibitor of an amorphous preparation as recited in present claim 10. For example, Slatter et al describes:

> The carriers may be any inert material, organic or inorganic, suitable, for administration, such as: water, gelatin, gum arabicum, lactose, microcrystalline cellulose, starch, sodium starch glycolate, calcium hydrogen phosphate, magnesium stearate, talcum, colloidal silicon dioxide, and the like.

However, there is no description of a substance having an ethylene oxide chain.

Even further, the technical object of Slatter and the means for solving the problem are different from the present invention which is to provide a stable pharmaceutical composition. Thus, there is no apparent reason for one of ordinary skill in the art to modify the disclosure of Slatter et al with a reasonable expectation of success. Even assuming that a composition could be prepared by preparing a compound for aerosol administration using solifenacin, as in Slatter et al, there is no description about a concrete means for solving the problem. For these additional reasons, the present invention is patentable over Slatter.

Fraser et al '822 and Fraser et al '890

As previously noted, Fraser et al '822 and Fraser et al '890 do not disclose, teach or suggest the existence of amorphous solifenacin or a composition of solifenacin or a salt thereof for use in a solid formulation Thus, for at least this reason, Fraser et al does not anticipate the present invention. Further, the Fraser et al references do not disclose teach or suggest a mixture of solifenacin or a salt thereof as an active ingredient together, i.e., mixed, with an inhibitor of an amorphous preparation as recited in present claim 10. For this additional reason the present invention is not anticipated by the Fraser et al references.

The Fraser et al references disclose a method for using an $\alpha_2\delta$ subunit calcium channel modulator and a compound having smooth muscle modulatory effects to increase effectiveness and lower the side effects. Solifenacin, which is a antimuscarinic agent, is disclosed as a smooth muscle modulating factor. The Fraser et al references describe many factors for controlling the smooth muscle and solifenacin is merely one of many drugs. However, one would have to pick and choose amongst the many drugs mentioned and such "picking and choosing" is inappropriate for an anticipation rejection. Additionally, there is no apparent reason to specifically select solifenacin.

Even further, one of ordinary skill in the art would not have been motivated to modify the disclosure of the Fraser et al references with a reasonable expectation of success in achieving the presently claimed invention.

For one reason, the technical object of Fraser et al and the means for solving the problem are different from the present invention which is to provide a stable pharmaceutical composition. The Fraser et al references ('822 at paragraph [295] and '890 at paragraph [294]) describe tablets etc., as the oral administration forms. At paragraph [297] of the '822 reference provided below (and paragraph [296] of the '890 not provided below) reference polyethylene glycol etc., is described as the binder. Moreover, it is described that the binder is used to impart adhesiveness to the compression molded tablet. In other words, as the oral administration form, the drug exists within the tablet and the binder such as polyethylene glycol is placed to surround the tablet, so that it is considered that the tablet and the binder exist without mixing with each other in the Fraser et al references.

> **[0297]** In addition to the active agent(s), then, tablets prepared for oral administration using the method of the invention will generally contain other materials such as binders, diluents,

> lubricants, disintegrants, fillers, stabilizers, surfactants, preservatives, coloring agents, flavoring agents and the like. Binders are used to impart cohesive qualities to a tablet, and thus ensure that the tablet remains intact after compression. Suitable binder materials include, but are not limited to, starch (including corn starch and pregelatinized starch), gelatin, sugars (including sucrose, glucose, dextrose and lactose), polyethylene glycol, propylene glycol, waxes, and natural and synthetic gums, e.g., acacia sodium alginate, polyvinylpyrrolidone, cellulosic polymers (including hydroxypropyl cellulose, bydroxypropyl methylcellulose, methyl cellulose, ethyl cellulose, hydroxyethyl cellulose, and the like), and Veegum.

On the other hand, the present specification provides:

> Preferably, solifenacin or a salt thereof is in contact with an inhibitor of amorphous preparation so that solifenacin or a salt thereof is distributed in a state of mixture. As in the case of using a pharmaceutical composition as a coating agent of solifenacin formulation wherein the active pharmaceutical ingredient, solifenacin or a salt thereof, is not in contact with or in mixture with such inhibitor of amorphous preparation so that it exists in a localized state (for example the inhibitor of amorphous preparation in accordance with the invention (PEG)), pharmaceutical preparations for example at a state such that solifenacin or a salt thereof is not in physical contact with a inhibitor of amorphous Preparation in an intermediate layer using other additives and the like are excluded.

From this description, it is apparent that the means for solution is different between the present invention and the Fraser et al references. Even assuming that solifenacin could be selected among the drugs described in the references, the position of the inhibitor of solifenacin preparation is different and there is no motivation to position the inhibitor to be mixed with the drug as in the present invention. Thus, there is no apparent reason for one of ordinary skill in the art to modify the disclosure of Fraser et al with a reasonable expectation of success of achieving the presently claimed invention. For this additional reason, the present invention is patentable over the Fraser et al references.

Saito et al

As previously pointed out, Saito et al neither discloses, teaches nor suggests the existence of amorphous solifenacin. Thus, for at least this reason, Saito et al does not anticipate the present invention. Additionally, Saito does not disclose, teach or suggest the presently claimed invention as recited in amended claim 10.

Saito et al describes a transdermal preparation comprising a substance having an ethylene oxide chain as an optional pharmaceutically acceptable excipient ([0033]) among many excipients. However, one would have to pick and choose among the many excipients to arrive at a substance having an ethylene oxide chain among many excipients and such "picking and choosing" is inappropriate in an anticipation rejection.

Even further, the technical object of Saito et al and the means for solving the problem are different from the present invention which is to provide a stable pharmaceutical composition. Thus, there is no apparent reason for one of ordinary skill in the art to modify the disclosure of Saito et al with a reasonable expectation of success. For this additional reason, the present invention is patentable over Saito et al.

In summary, none of the references teaches or suggests all elements of the presently claimed invention. Accordingly, the invention of amended claim 10 is both novel and non-obvious. Claims 12 and 17 depend directly, or indirectly from claim 10 and are patentable for at least the same reasons.

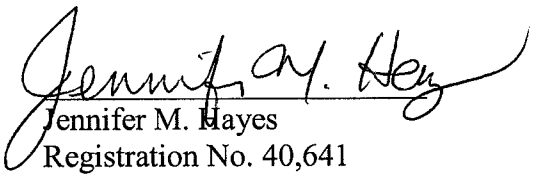
Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 102.

V. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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